	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.009 Version 1

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Article:	Annex: VII Module C2		Clause:	RfU sheet 007, 2B(iii) and 2B(iv)

Key words:

Failure of C2 samples

Question:

What are the necessary actions following failures when samples are taken as required by recommendation for use sheet 007, sections 2B(iii) and 2B(iv), assessment of non-homogeneity?

Solution:

The following steps should be taken:

1. Manufacturer asked to investigate the failure(s) and advise the notified body of their findings.

2. The manufacturer must inform the notified body whether or not they consider the product acceptable without modification or if the product is to be modified, and how.

3. Notified body to then determine what level of additional testing is required

4. Additional samples requested from the manufacturer and tested under the authority of the notified body

5. If additional samples pass the required testing, C2 considered completed.

6. If additional samples fail, steps 1 to 4 repeated.

7. If second set of additional samples fail, C2 certification to be withdrawn / not re-issued.

NOTE:

1. If the module C2 body is not the module B body, module B body to be kept informed throughout the process.

2. Notifying authorities to be informed of failures.